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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,816	10/19/2005	Lydie Bougueleret	4-33636A/GEP	7751
NOVARTIS INSTITUTES FOR BIOMEDICAL RESEARCH, INC. 400 TECHNOLOGY SQUARE			EXAMINER	
			CHEU, CHANGHWA J	
CAMBRIDGE, MA 02139			ART UNIT	PAPER NUMBER
			1641	
			MAIL DATE	DELIVERY MODE
			03/04/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)			
	10/553,816	BOUGUELERET ET AL.			
Office Action Summary	Examiner	Art Unit			
	JACOB CHEU	1641			
The MAILING DATE of this communication appeariod for Reply	pears on the cover sheet with the c	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REPL WHICHEVER IS LONGER, FROM THE MAILING D  - Extensions of time may be available under the provisions of 37 CFR 1.' after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period  - Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailin earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 136(a). In no event, however, may a reply be timwill apply and will expire SIX (6) MONTHS from e, cause the application to become ABANDONE	lely filed the mailing date of this communication. (35 U.S.C. § 133).			
Status					
<ol> <li>Responsive to communication(s) filed on 10 J</li> <li>This action is FINAL.</li> <li>Since this application is in condition for alloward closed in accordance with the practice under the second secon</li></ol>	s action is non-final. ince except for formal matters, pro				
Disposition of Claims					
4) ☐ Claim(s) 1-20 is/are pending in the application 4a) Of the above claim(s) 1-7 and 9-20 is/are v 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 8 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/o	vithdrawn from consideration.				
9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) accomposed and applicant may not request that any objection to the Replacement drawing sheet(s) including the correct to by the Example 2.	cepted or b) objected to by the Education of the drawing(s) be held in abeyance. See tion is required if the drawing(s) is objected to be seen	e 37 CFR 1.85(a). ected to. See 37 CFR 1.121(d).			
Priority under 35 U.S.C. § 119					
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>					
Attachment(s)  1) Motice of References Cited (PTO-892)	4) ☐ Interview Summary				
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	ite			

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## **DETAILED ACTION**

### Election/Restrictions

1. Applicant's election without traverse of Group III, claim 8, in the reply filed on 1/10/2008 is acknowledged.

2. Currently, claim 8 is under examination. Claims 1-7 and 9-20 are withdrawn from further consideration.

# Claim Rejections - 35 USC § 103

- 3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 4. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  - 1. Determining the scope and contents of the prior art.
  - 2. Ascertaining the differences between the prior art and the claims at issue.
  - 3. Resolving the level of ordinary skill in the pertinent art.
  - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 5. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yanagita (I) (US 6852692) in view of Layton et al. (US 6184370).

Yanagita et al. teach an isolated polypeptide, i.e. SEQ ID No. 2 which has the same amino acid sequence as the recited SEQ ID No. 1. Yanagita et al. also teach using

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recombinant DNA technique for producing said polypeptide for further analysis (Col. 5, line 65- Col. 6, line 10). However, Yanagita et al. do not explicitly teach fusing the SEQ ID No. 2 with a heterologous polypeptide.

Layton et al. teach using recombinant technique to manufacture target polypeptide. Layton et al. teach fusing the target polypeptide with a heterologus polypeptide in the expression vector, e.g. GST (glutathione-S-transferase) for better selection and the GST is also described and used by Applicant in the specification (See Figure 4, Col. 1, line 20-25). Layton et al. indicate that such recombinant technique is routinely practiced and well-known in the art.

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to have provided Yanagita et al. with various heterologous fusing polypeptide in the recombinant DNA technique for manufacturing target polypeptide, such as GST as taught by Layton et al. for better selection and identification. One ordinary skill in the art would have been motivated to use GST since it has been known and widely practiced in the field, and it merely requires routine skill in the art for performance.

6. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bridon et al. (WO 200069900) in view of Layton et al..

Bridon et al. teach an isolated polypeptide, i.e. SEQ ID No. 939 which has the same amino acid sequence as the recited SEQ ID No. 3. Note, the recited language uses an open term "comprising". The SEQ ID No. 939 in Bridon et al. reference has 48 amino acid residues encompassing the recited SEQ ID No. 5 which has 13 amino acid residues. Bridon et al. also teach using recombinant DNA technique for producing said polypeptide for further analysis (Col. 5, line 65- Col. 6, line 10). However, Bridon et al. do not explicitly teach fusing the SEQ ID No. 3 with a heterologous polypeptide.

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As discussed above, Layton et al. reference teaches fusing targeted polypeptide with a heterologous GST in the expression vector for producing the target polypeptide. It would have been obvious to one ordinary skill in the art at the time the invention was made to have provided Bridon et al. with the GST fusing heterologous polypeptide to manufacture the target polypeptide for better selection and identification.

7. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yanagita (II) (US 20070161555) in view of Layton et al..

Yanagita et al. teach an isolated polypeptide, i.e. SEQ ID No. 2 which has the same amino acid sequence as the recited SEQ ID No. 2. Note, the recited language uses an open term "comprising". The SEQ ID No. 2 in Yanagita et al. reference has 185 amino acid residues encompassing the recited SEQ ID No. 2 containing 164 amino acid residues. Yanagita et al. also teach using recombinant DNA technique for producing said polypeptide for further analysis (Col. 5, line 65- Col. 6, line 10). However, Yanagita et al. do not explicitly teach fusing the SEQ ID No. 2 with a heterologous polypeptide.

As discussed above, Layton et al. reference teaches fusing targeted polypeptide with a heterologous GST in the expression vector for producing the target polypeptide. It would have been obvious to one ordinary skill in the art at the time the invention was made to have provided Yanagita et al. with the GST fusing heterologous polypeptide to manufacture the target polypeptide for better selection and identification.

8. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kitamura et al. (Biochem Biophys Res Commu. 1993 Vol. 194, page 720-725) in view of Layton et al..

Kitamura et al. teach an isolated polypeptide having 185 amino aicd residues which encompasses the recited SEQ ID No. 4 (27/185) and SEQ ID No. 6 (14/185). However, Kitamura et al. do not explicitly teach fusing the polypeptide with a heterologous polypeptide.

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As discussed above, Layton et al. reference teaches fusing targeted polypeptide with a heterologous GST in the expression vector for producing the target polypeptide. It would have been obvious to one ordinary skill in the art at the time the invention was made to have provided Kitamura et al. with the GST fusing heterologous polypeptide to manufacture the target polypeptide for better selection and identification.

#### Conclusion

## 9. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACOB CHEU whose telephone number is (571)272-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jacob Cheu
Examiner
Art Unit 1641

/Long V Le/

Supervisory Patent Examiner, Art Unit 1641